

**REMARKS**

Claims 1-59 are pending. Claims 1-11, 16-31, 33-51 and 57 have been withdrawn from consideration. Applicants reserve the right to file one or more divisional applications directed to the subject matter of the non-elected claims.

The amendments to the pending claims are made to more clearly define the inventions. It is submitted that the amendments introduce no new matter and entry of the same is respectfully requested. By these amendments, the Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which the Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

**I. Rejection of claims 12-15, 32 and 52 under 35 U.S.C. § 102(b) as anticipated by Tuck et al.**

The Examiner rejected claims 12-15, 32 and 52 under 35 U.S.C. § 102(b) "as being anticipated by Tuck et al. (Blood (1994) 84(7); 21-82-2188." Paper No. 17 at page 3. Applicants respectfully traverse.

To support an anticipation rejection under 35 U.S.C. §102(b), the Examiner must demonstrate that each and every element of a claimed invention is disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). In other words, to anticipate the claim must encompass and empower a patentee or assignee to exclude others from making, using, or selling a product described in said printed publication. *Helifix Ltd. v. Blok-Lok Ltd.*, 54 U.S.P.Q.2d 1299, 1304 (Fed. Cir. 2000). Indeed, the printed publication must describe an applicant's claimed invention sufficiently to have placed a person of ordinary skill in the art in the field of the invention in possession of it. *See generally In re Paulson*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994).

Without acquiescing to the propriety of the Examiner's rejection and in order to facilitate prosecution of the pending application, Applicants have amended claim 12 by combining the claim with the subject matter of withdrawn claim 14. Further, Applicants have amended claim 12 to specify the nature of the heterologous molecule to include the group consisting of a molecule of the major histocompatibility complex, a recombinant molecule of the major histocompatibility complex, an antigen, a receptor ligand, a ligand receptor, a nucleic acid, a pharmacological product, a tracer and a purification peptide. Claim 13 has

been deleted. Claims 15 and 32 have been amended to recite the new wording of claim 12 and now respectively refer to claim 12 and to claim 12 or 15.

Tuck relates to the expression of M-CSF in COS-1 cells and vesicles derived from such cells. The Examiner states that “while Tuck et al. does not specifically teach that the isolated vesicles are mastocyte-derived, absent a showing to the contrary regarding specific properties not present in vesicles derived from other sources, membrane vesicles derived from mastocytes are not seen as being different from vesicles derived from other eukaryotic cell types.” *Id.* Applicants disagree.

Indeed, Tuck states that “[D]epending on the cellular origin of extracellular vesicles, diverse functions are mediated by the shedding process... Whether a subset of vesicles shed instead from COS cells transfected with cDNA for M-CSF expresses the activity (analogous to mBPA expression by MHC class-II antigen-bearing vesicles) or whether all shed vesicles express activity is unknown.” Tuck et al., at page 2186 (emphasis added). Therefore, Applicants assert that Tuck clearly indicates that the origin of vesicles influences their compositions and that the biological activity of the recombinant factor is not clearly known. Therefore, nowhere does Tuck teach or suggest an isolated membrane vesicle that is secreted from a mastocyte or mastocyte derived cell, which comprises one or more heterologous molecules of interest.

Therefore, because Tuck does not teach each and every element of the claimed inventions, claims 12-15, 32 and 52 are not anticipated under 35 U.S.C. § 102(b). Accordingly, Applicants respectfully request that the present rejection be reconsidered and withdrawn.

## **II. Rejection of Claim 1, 53-56, 58 and 59 under 35 U.S.C. § 103(a) over Tuck in view of Xu**

The Examiner rejected claims 1, 53-56, 58 and 59 under 35 U.S.C. § 103(a). Paper No. 17 at page 4. Specifically, the Examiner alleges that these claims are “unpatentable over Tuck et al (Blood (1994) 84(7); 2182-2188... in view of Xu (Molec. Immunol. (1994) 21(10):723-731).” *Id.* Applicants respectfully traverse.

To maintain a proper rejection under 35 U.S.C. § 103, the USPTO must meet four conditions to establish a *prima facie* case of obviousness. First, the USPTO must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the USPTO must show that

the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaack*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the USPTO must show the suggestion, teaching, or motivation to combine the prior art references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

The Examiner alleges that "it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of Xu regarding the recombinant expression of DR1  $\alpha$  and  $\beta$  chains with the teachings of Tuck to study the interaction of vesicle-bound MHC molecules with effector CD4+ T cells." *Id.* at page 4. First, Applicants respectfully submit that claim 1 has been withdrawn and should not be considered in the present 35 U.S.C. § 103(a) rejection. Next, Applicants assert Tuck is deficient as a primary reference as discussed above in Applicants traversal of the §102.

Xu, as a secondary reference, does not remedy the deficiencies of Tuck. Xu describes the recombinant expression of HLA DR1  $\alpha$  and  $\beta$  chains in COS-1 cells. Nowhere, however, does Xu teach or suggest membrane vesicles expressing recombinant MHC class II molecules. Further, nowhere does Xu teach or suggest membrane vesicles according to the invention secreted by a mastocyte or a mastocyte derived cell or a composition comprising such vesicles.

Neither Tuck nor Xu teaches or suggests an isolated membrane vesicle that is secreted from a mastocyte or mastocyte derived cell, and which comprises one or more heterologous molecules of interest. Therefore, Tuck, either alone or on combination with Xu, does not support a rejection under 35 U.S.C. § 103. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, and Applicants respectfully request that the present rejection be reconsidered and withdrawn.

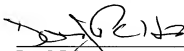
**CONCLUSION**

Applicants have properly accommodated each of the Examiner's grounds for rejection. Applicant submits that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited.

If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully submitted,

23 December 2003

  
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Don J. Pelto  
Reg. No. 33,754

Preston Gates Ellis & Rouvelas Meeds LLP  
1735 New York Avenue, NW, Suite 500  
Washington, DC 20006  
Telephone: (202) 628-1700  
Facsimile: (202) 331-1024

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Figure 1

FIG 1A

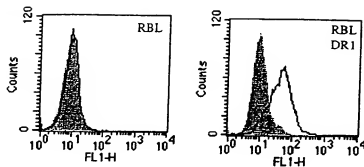


FIG 1B

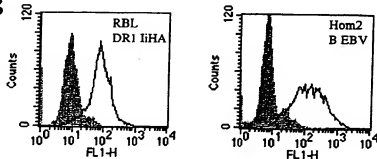


FIG 1C

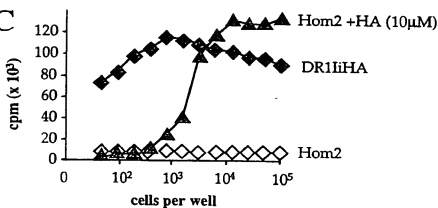


FIG 1D

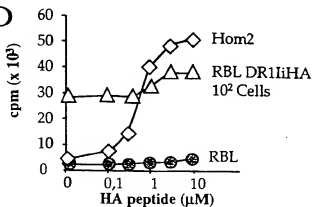




FIG 2A

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FIG 2 B

DR1iiHA

HOM2

cells exosomes

47 -



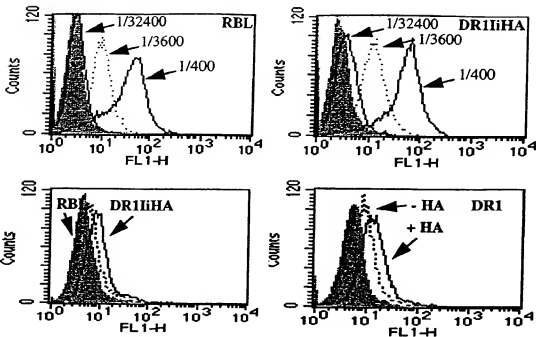
← β DR1

30 -

Figure 2

Figure 3

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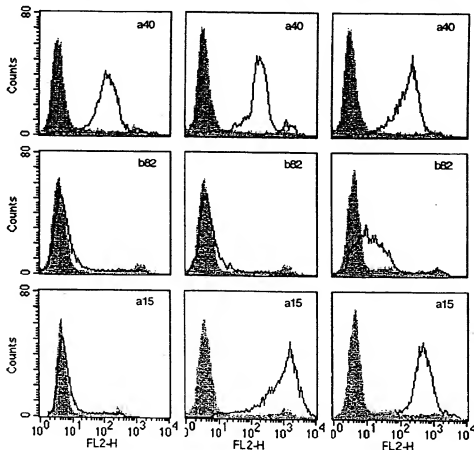


RBL-2H3

RBL-2H3 DR1

RBL DR111HA

FIG 3 C





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Figure 4

FIG 1 A



FIG 1 B



FIG 3 C

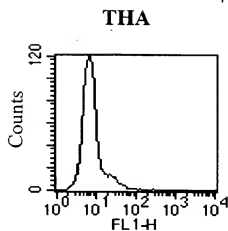


FIG 4 D

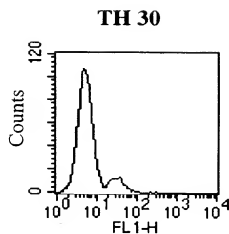






FIG 5A

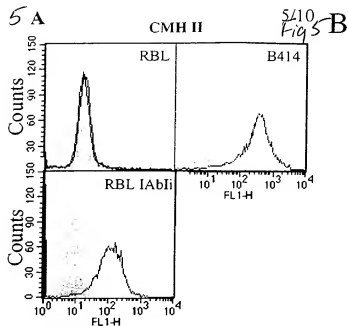


FIGURE 5

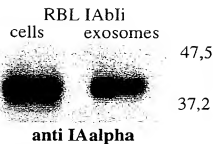
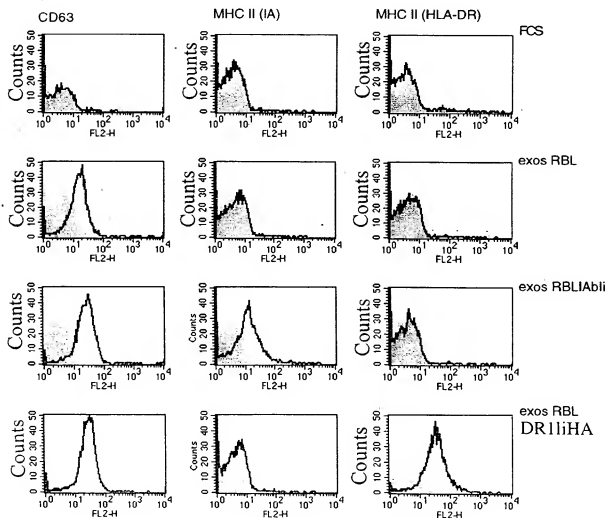


FIG 5C



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FIG 7A

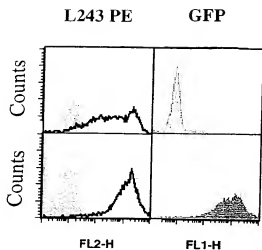


FIG 7B

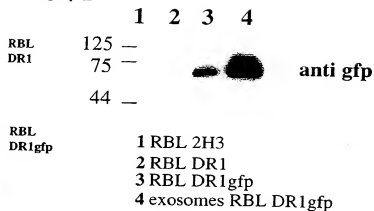


FIG 7C

Aldehyde/sulfate Latex beads

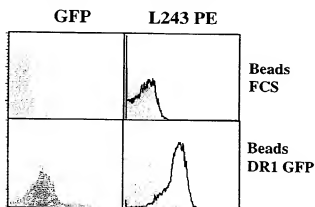


Figure 7

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Figure 8

Jurkat

T-HA

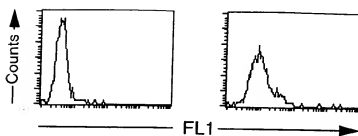


FIG 8B

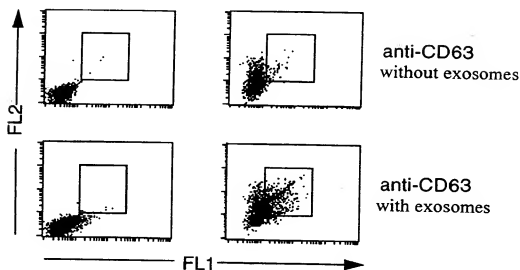


FIG 8C

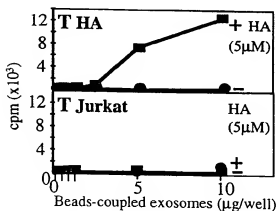


FIG 9 A

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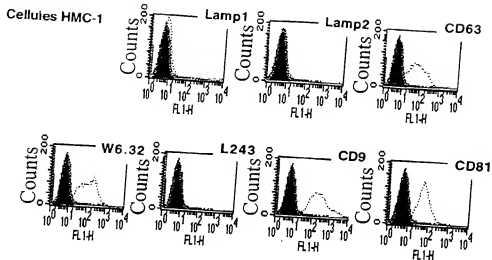


FIG 9 B

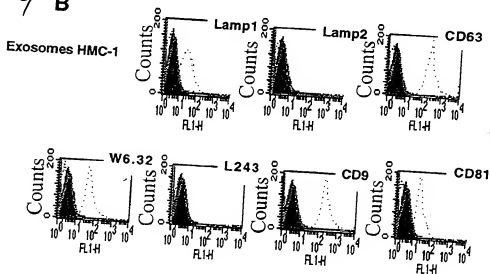


FIG 9 C

Lysat Exosomes  
 HMC-1 HMC-1  
 10µg 3µg 10µg 3µg  
 Exosomes HMC-1

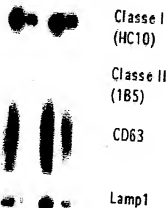


Figure 9